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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,530	11/13/2003	Andrew Thomas Forsberg	47563.0014	9304
7590 03/22/2005				
L. Grant Foster HOLLAND & HART LLP 555 - 17th Street, Suite 3200 P.O. Box 8749 Denver, CO 80201		EXAMINER SAM, CHARLES H		
		ART UNIT PAPER NUMBER 3731		

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,530	Applicant(s) FORSBERG ET AL. 67	
	Examiner Charles H. Sam	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, “the first indicator coupled with the first inlet port” in claim 1, “the second indicator coupled with the second inlet port” in claim 2, “at least the third indicator coupled with at least the third inlet port” in claim 5, “the second inlet port and the second indicator, the first inlet port and the first indicator, at least the third inlet port and at least the third indicator” in claim 12, and “the penetration gauge comprising an indicator” in claims 35 and 36, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1,2,5,12,35 and 36 are objected to because of the following informalities: "the first indicator coupled with the first inlet port" in claim 1, "the second indicator coupled with the second inlet port" in claim 2, "at least the third indicator coupled with at least the third inlet port" in claim 5, "the second inlet port and the second indicator, the first inlet port and the first indicator, at least the third inlet port and at least the third indicator" in claim 12, and "the penetration gauge comprising an indicator" in claims 35 and 36, cannot be found in the drawings. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-11 provide for the use of the indicator, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 6-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,3,4,13-15,22-23 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Tassel et al. 6,193,670. Van Tassel discloses a vascular insertion assembly comprising an insertion sheath 60 having an inside diameter and comprising a sheath distal end 64 and a sheath proximal hub 62, the dilator 12 sized to fit in the inside diameter of the insertion sheath 60 comprising a dilator distal end 17 and a dilator proximal end, a first inlet port 52 located about the sheath distal end, and the first indicator coupled with the first inlet port 52 such that when the first inlet port penetrates a vessel the first indicator provides indication.

Regarding claim 3, Van Tassel discloses the first inlet port comprising a plurality of inlet ports.

Regarding claim 4, Van Tassel discloses the plurality of offset inlet ports.

Regarding claims 13-14, note figures 1-3.

Regarding claim 15, note figures 4-6.

Regarding claims 22-23, note figures 1-3,5 and 6.

Regarding claim 35, see column 5, lines 13-32.

2. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. 6,193,670 in view of Peters 5,725,496. Van Tassel discloses the

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invention as claimed except for a pressure gauge. However, Peters discloses a differential pressure gauge 29. It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Van Tassel by including a differential pressure gauge in view of Peters to indicate the pressure.

Regarding claims 25-27, it is very well known in the art to use a ball float gauge.

3. Claims 16-21,29-34,37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. 6,179,863. Kensey discloses a vascular insertion assembly as shown in figures 30-33 comprising an insertion sheath 28 having a sheath distal end and a sheath proximal end, a dilator 600 having a dilator distal end and a dilator proximal end; the dilator 600 sized to fit in the insertion sheath 28; a first inlet port 506 located about the dilator distal end; a second inlet port 504 located about the sheath distal end; a first drip hole in fluid communication with the first inlet port; and a second drip hole in fluid communication with the second inlet port 28D.

Regarding claim 29, note figure 32.

Regarding claims 30 and 31, a plurality of first inlet ports is just a duplication of the first inlet port.

Regarding claims 32-34, a plurality of second inlet ports is just a duplication of the second inlet port.

Regarding claims 37 and 38, note figure 1.

Regarding claims 38 and 39, the second inlet port or the third inlet port is just a duplication of the first inlet port, and the second or third drip hole is just a duplication of the first drip hole.

Regarding claims 16-18, 20-21, note figures 31-33.

Regarding claim 19, note figure 28.

4. Claim 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. 6,193,670 in view of Seward et al. 6,547,803. Van Tassel discloses the invention as claimed except for a sensor. However, Seward discloses a device 10 including a sensor, column 8, lines 16-27. It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Van Tassel by including a sensor in view of Seward for measuring the flow of blood.
5. Claim 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. 6,193,670 in view of O'Neill et al. 5,807,326. Van Tassel discloses the invention as claimed except for a means for providing penetration information. However, O'Neill discloses a means for providing penetration information, column 5, lines 30-50; column 14, lines 10-22, lines 40-55. It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Van Tassel by including a means for providing the depth of penetration in view of O'Neill to facilitate proper placement of the device.
6. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. 6,193,670 in view of O'Neill et al. 5,807,326 as applied to claim*** above, and further in view of Seward et al. 6,547,803. Van Tassel in view of O'Neill discloses the invention as claimed except for a sensor. However, Seward discloses a device 10 including a sensor, column 8, lines 16-27. It would have been obvious to one having an

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ordinary skill in the art at the time the invention was made to modify Van Tassel by including a sensor in view of Seward for measuring the flow of blood.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles H. Sam whose telephone number is (571) 272-4703. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

chs
March 14, 2005


KEVIN T. TRUONG
PRIMARY EXAMINER